Interagency Registry of Mechanically Assisted Circulatory Support

Parent Consent (Child Assent) Form for Child’s Participation in Research

Sponsor: The National Heart, Lung, and Blood Institute (NHLBI)
Contract #HHSN 268201100025C

Principal Investigator: (Insert local Principal Investigator)

Phone number: (Insert local Principal Investigator phone number)

INFORMED CONSENT

You/your child is being asked to take part in this registry because

- He or she is receiving, or has received, a mechanical circulatory support device (MCSD).

A registry is a place where data, records, and sometimes laboratory samples are kept and made available for research. This registry will collect and analyze clinical information and laboratory data from all pediatric patients who are having an MCSD implanted for supporting the circulation. This registry includes approximately 115 hospitals within the United States for a period of nine years starting March 1, 2006. The broad purpose of the registry is to gather information to help understand and improve the lives of patients with advanced heart failure.

YOUR PARTICIPATION IS VOLUNTARY

This is a consent form. It gives you/your child information about the registry. You are free to ask questions about this registry at any time. If you agree to take part in this registry, you will be asked to sign this consent form. The registry coordinator will make you a copy of this form to keep.
Before you learn about the registry, it is important that you know the following:

- Your participation is totally voluntary and will not affect your child’s care in any way.
- You may decide not to take part or to leave the registry at any time without losing your medical care benefits.

WHAT IS THE PURPOSE OF THIS REGISTRY?

Over the last twenty five years, mechanical circulatory support devices (MCSD) have been developed to help the failing heart. In the last ten years, many of these devices have been used in infants, children, and teenagers. MCSDs have been used successfully to support patients until they get a heart transplant. In adults, they have also been used as treatment until recovery as well as for permanent implantation (placement in the body) or "destination therapy". It is expected that the number of MCSD implantations will increase in future years. This registry will allow scientists to study patient characteristics, device function, implantation procedures, and the possible adverse events that can arise with MCSD placement. The registry will also be linked with other existing databases, such as the transplant registry (SRTR) as well as the Pediatric Heart Transplant Study registry. This will allow us to understand how the MCSD affects transplant patients.

WHAT DO I HAVE TO DO IF I AM IN THIS REGISTRY?

If you decide to take part in this study and sign the informed consent, you will:

- Allow research staff within the hospital to review your child’s medical chart for information on his or her medical history and medications he or she has taken or may be currently taking. This information will be entered it into a confidential database.
- Allow research staff within the hospital to collect age appropriate quality of life questionnaires from your child.
- Complete the parent quality of life questionnaire.
- If your child is 10 years of age or older, you will allow research staff to complete a limited functional capacity test (how far your child can walk in 6 minutes and how fast your child can walk 15 feet)

The medical chart review and abstractions will be done:
- before your child’s implant,
- 1 week after implant,
- 1 month after implant,
- 3 months after implant,
- 6 months after implant and every six months thereafter.

The brief quality of life questionnaire and walk tests will be done:
- before your child’s implant,
- 3 months after implant,
- 6 months after implant and every six months thereafter.

If your child receives a heart transplant, his or her “follow-up” will occur in the UNOS (United Network or Organ Sharing) transplant database. You will allow your child’s registry data to be merged with transplant data and analyzed by registry investigators. If your child’s MCSD is removed and your child has recovered, you will have your child’s medical information followed for one more year after removal.

**HOW MANY PEOPLE WILL TAKE PART IN THIS REGISTRY?**

It is possible that about 10,000 people will take part in this registry:
- Over 1,000 patients per year for 9 years.
- About 20-30 children per year.
- The more than 1,000 patients per year will come up to 115 participating hospitals nationwide.

**HOW LONG WILL I BE IN THIS REGISTRY?**

Participation in the registry begins when this consent form is signed and continues for as long as your child has a MCSD implanted. Following transplant or death, data collection will stop. If your MCSD is removed due to recovery, your medical information will be collected for one more year. If you transfer to another institution that participates in this registry, you will be asked to sign another consent form for continued participation. You/your child are free leave the registry or withdraw your consent at any time, even after you have signed this consent. If the hospital that implanted your child’s MCSD discontinues participation in the registry, then your participation in this registry will be terminated.

**WHAT ARE THE RISKS OF THE REGISTRY?**

The risks for participation in this registry are considered very small. The data collection will be confidential and there will not be risk to you. The quality of life questionnaire and a limited functional capacity test (how far you can walk in 6 minutes and how fast you can walk 15 feet) for patients 10 years of age or older will take some of your time - approximately 20 minutes. There are some questions that some may consider sensitive. You can choose not to answer any questions that you do not want to.
WHAT ARE THE BENEFITS OF THE REGISTRY?

There is no direct benefit to you or your child from being in this registry. However, knowledge gained from the registry may help those with advanced heart failure. A potential indirect benefit is that you may help doctors and scientists better understand how the MCSD improve or do not improve life for heart failure patients.

You will be given any new information during the course of this registry concerning significant treatment findings that may affect your willingness to continue your child’s participation.

WHAT ABOUT CONFIDENTIALITY?

All information collected in this registry will be held confidential to the extent permitted by law. No published or unpublished report or visual or speaking presentation about this registry will include any material that will identify your child as a participant in this registry. Your child’s name, date of birth, and only the last 5 digits of his or her social security number, and hospital medical record number (optional) will be entered into the confidential INTERMACS database. This is so your data can be linked with the transplant database in the event that you receive a heart transplant. In the event that a social security number has not yet been issued for your child, the last 5 digits of the transplant wait list number may be used.

Your child’s confidential information will not be available to anyone outside of INTERMACS, and only UNOS employees that work directly with the registry will be exposed. INTERMACS complies with all national patient privacy regulations. All of their data systems feature multiple levels of security, which protect patient data by the most stringent requirements. In addition, all INTERMACS employees have passed federal HHS background checks for government clearance. Access to the production databases are on a need-to-know access only.

In certain circumstances, (name of institution’s) Institutional Review Board (IRB) may request a copy of your child’s records. The job of the IRB is to make sure volunteers in studies and registries are protected. If they ask for a copy of your child’s records, we will give it to them. In addition, under the guidelines of the Federal Privacy Act, the sponsoring agency, the National Heart Lung and Blood Institute and the study monitors may also periodically request to review your child’s records. Their job is to make sure that the registry is doing what it is supposed to and that volunteers are protected. If they ask to see your records, we will let them.

Investigators for INTERMACS, NHLBI, representatives from the MCSD manufacturer, the Food and Drug Administration (FDA) and centers for Medicare and Medicaid services (CMS) will use your information to better understand how the MCSD improve or do not improve life for heart failure patients.
To help us protect your child’s privacy, INTERMACS has obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify your child, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify your child, except as explained below. No voluntary disclosures will be made.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of Federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

The National Heart, Lung, and Blood Institute will obtain information from this clinical study under data collection authority Title 42 U.S.C. 285b.

You should understand that this does not prevent you or a member of your family from releasing information about your child’s involvement in this registry if you want to. Note however, that if an insurer or employer learns about your child’s participation, and you say it is all right for them to have this research information, the investigator may not withhold this information from them. This means that you and your family must also actively protect your own privacy. You have to be careful about whom you permit to look at your research information.

WHAT ARE THE COSTS TO ME?

There are no costs to you for participation in this registry. As usual, you and/or your insurance company will be responsible for any costs that are part of your child’s care.

WILL I RECEIVE ANY PAYMENT?

You/your child will not be paid or offered any other compensation for participating in this registry. You/your child will not receive any medications through this registry.

WHAT HAPPENS IF I AM INJURED?

There is minimal risk associated with this registry data collection. In the rare instance that you/your child are injured as a result of being in this registry, you/your child will be given immediate treatment. The cost for this treatment will be charged to you or your insurance company. There is no program for compensation through either this institution or the National Institutes of Health (NIH).
WHAT ARE MY RIGHTS AS A RESEARCH SUBJECT?

Taking part in this registry is completely voluntary. You may choose not to take part in this registry or leave this registry AT ANY TIME without penalty, loss of benefits, or change in your present or future care. You and your child will be treated the same no matter what you decide. We will tell you about new information from this or other studies that may affect your child’s health, welfare, or willingness to stay in this registry. If you want the results of the registry, tell the study staff. You are not giving up any of your legal rights by signing this consent form.

WHAT DO I DO IF I HAVE QUESTIONS OR PROBLEMS?

If you/your child ever have questions about this registry or in case of research-related injuries, you should contact (name of investigator) at (telephone number). If you have questions about research subjects’ rights, you can call (name and title of IRB member) at (telephone number).

STATEMENT OF CONSENT

(NOTE: This is only a suggested signature format. Sites may use their own signature page.)

The details of this registry have been explained to you and you have been given the opportunity to ask any questions you wish regarding this registry. The doctor or other person performing this research registry has told you that your participation in this registry is voluntary. You may be a subject in it only if you wish, and you may refuse to participate or stop participating at any time without any way affecting your future treatment at this hospital, or your future relations with the hospital or its employees. By signing this consent form, you are voluntarily agreeing to take part in this registry and giving your permission for the registry investigators to collect and use the information and specimens needed for the purposes of this registry. If you voluntarily agree to take part in this registry, please sign your name below.

_______________________          _______________________         ______________
Participant Name (print)            Participant Assent   Date

__________________________  ________________________ ______________
Parent/Legal Guardian Name (print) Parent/Legal Guardian Signature  Date

_______________________         ___________________________ _______________
Witness Name (print)             Witness Signature      Date

PI or Designee’s statement:

I have reviewed this registry and the consent form with the subject. To the best of my knowledge, she understands the purpose, procedures, risks, and benefits of the registry.

PediMACS Informed Consent Version Date: 7/18/2012
NOTE: This consent form with the original signatures MUST be retained on file by the principal investigator. A copy must be given to the volunteer. A copy should be placed in the volunteer's medical record, if applicable.